

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Edith DELLACHERIE et al. Group Art Unit: 1615

Application No.: 10/522,333 Examiner: J. PALENIK

Filed: January 25, 2005 Docket No.: 122536

For: PARTICLES WHICH ARE SURFACE COATED WITH HYALURONAN OR ONE OF

THE DERIVATIVES THEREOF AND THE USE OF SAME AS BIOLOGICAL

VECTORS FOR ACTIVE SUBSTANCES

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In reply to the December 4, 2007, Restriction and Election of Species Requirement, Applicants provisionally elect Group I, claims 1-20, and elect as a Species saturated alkyl chains having a chain length ranging from 15-20 carbon atoms and nanoparticles, with traverse. At least claims 1-7, 9-18, and 20 read on the elected species. At least claim 1 is generic to all species.

National stage applications filed under 35 U.S.C. §371 are subject to unity of invention practice as set forth in PCT Rule 13, and are not subject to U.S. restriction practice. See MPEP §1893.03(d). PCT Rule 13.1 provides that an "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 states:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a

technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention may be apparent "a priori," that is, before considering the claims in relation to any prior art, or may only become apparent "a posteriori," that is, after taking the prior art into consideration. See MPEP §1850(II), quoting International Search and Preliminary Examination Guidelines ("ISPE") 10.03. Lack of a priori unity of invention only exists if there is no subject matter common to all claims. Id. If a priori unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established a posteriori by showing that the common subject matter does not define a contribution over the prior art. Id.

Furthermore, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims, as stated in ISPE 10.06:

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4).

See also MPEP §1850(II). ISPE 10.07 further provides:

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

See also MPEP §1850(II).

Each of claims 2–20 variously depends from claim 1 and, thus, requires all of the elements of claim 1. Accordingly, all the claims share common subject matter and, therefore, a priori unity of invention exists between all the claims. Thus, for the present application, a

lack of unity of invention may only be determined *a posteriori*, or in other words, after a search of the prior art has been conducted and it is established that all the elements of independent claim 1 are known. *See* ISPE 10.07 and 10.08.

The Office Action does not establish that each and every element of claim 1 is known in the prior art. Claim 1 recites that the core is based on "at least one biodegradable organosoluble polymer." The core particle taught by U.S. Patent No. 5,753,234 is not based on an organosoluble polymer. See U.S. Patent No. 5,753,234, col. 5, line 66 to col. 6, line 2, reproduced below for convenience.

The water-soluble substance used for the preparation of the core particle does not bring about an undesirable interaction with the protein antigen and is practically insoluble in the organic solvent used in the coating step.

Therefore, because U.S. Patent No. 5,753,234 does not teach each and every element of claim 1, Applicants respectfully submit that a lack of unity of invention has not been established and, thus, a restriction requirement based on a lack of unity of invention is improper.

Although unity of invention practice under PCT Rule 13 recognizes that alternate forms of an invention may be present in separate independent claims, or in a single claim, restriction between distinct embodiments of a single claim may only be required if there is a lack of unity of invention in that claim, or, in other words, the distinct embodiments share no common subject matter that defines a contribution over the prior art. *See* ISPE 10.09; MPEP §1250(II).

Again, the Office Action fails to establish that a lack of unity of invention exists between distinct embodiments of claim 1. Instead, the Office Action asserts, "there is no special technical feature because U.S. Patent 3,890,442 teaches the oral administration of microencapsulated 1,2,4-triazole antimycotic composition in tablet, powder or gelatin sheath form." See Office Action, page 4. However, claim 1 recites:

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1. A particle in which the core is based on at least one biodegradable organosoluble polymer, characterized in that it is at least partially surface-coated with at least one hyaluronan or with one of its derivatives, said hyaluronan being a water-soluble amphiphilic hyaluronan, the carboxylic functions of which are in part converted so as to form hydrophobic groups.

The Office Action fails to show where <u>any</u> of the positively recited elements of claim 1 are found in U.S. Patent 3,890,442. Therefore, the Office Action has not met its burden in establishing a lack of unity of invention.

Because the Office Action has not demonstrated a lack of unity of invention under the rules, the restriction and election of species requirements are improper. Reconsideration and withdrawal of the restriction and election of species requirements are respectfully requested.

Respectfully submitted,

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